



#4

PATENT  
Attorney Docket No. KAP 101 DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Aaron V. Kaplan, M.D., et al

Serial No.: 10/002,329

Filed: November 1, 2001

Group Art No.: 3763

Examiner: Not yet Assigned

For: METHODS AND APPARATUS FOR  
PERICARDIAL ACCESS

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

"Express Mail" Mailing Label No.: EL845497803US

Date of Deposit January 24, 2002

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office Box Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Office of Initial Patent Examination's Customer Service Center, Assistant Commissioner for Patents, Washington, D.C. 20231

NAME Jeannie Rapstad

SIGNATURE Jeannie Rapstad

**Response to Notice of Omitted Items and**  
**Preliminary Amendment**

Office of Initial Patent Examination's  
Customer Service Center  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Please amend the application as follows:

**Drawings**

Please substitute the enclosed corrected sheet of formal drawings containing Figs. 5E-7 for the previously submitted sheet containing Figs. 5E-7A.

**Rewritten Specification in Clean Form**

Please substitute the following paragraph for the paragraph beginning on page 8, line 30 of the specification:

--As illustrated in Fig. 7, the access tube 50 can be used to access a pericardial space PS from a subxiphoid approach. A patient's heart H underlies the sternum S beneath the chest wall CW, as illustrated in Fig. 7. The access tube 50 can be introduced beneath the inferior end of the sternum S to approach the parietal pericardium PP. The penetrating elements 56 can thus engage the parietal pericardium and draw it away from the visceral pericardium VP. The access device 14 can then be introduced through the access tube 50 and into the enlarged pericardial space PS'. The access device 14 can be used for introducing a guidewire or any of the other purposed described above.--

**Rewritten Claims in Clean Form**

Please amend claim 21 to read as follows:

21. (Amended) A kit for accessing the pericardial space between the visceral and parietal pericardium, said kit comprising:
  - an access tube having a distal end which can be selectively embedded into tissue; and
  - instructions for use setting forth a method for accessing an anatomic space having a wall with an outer surface, said method comprising:

embedding a distal end of an access tube into the outer surface;

drawing the access tube proximally to raise the wall over the anatomic space and to enlarge the anatomic space; and

introducing an access device through the access tube, penetrating the wall and into the anatomic space while the access tube stabilizes the wall.

**Remarks**

This preliminary amendment is to clarify that claim 21, as filed, was an independent claim and to respond to a Notice of Omitted Items.

This application is a divisional application based on Serial No. 09/397,392, filed September 16, 1999. The present application includes claims 16-21 of the '392 application.

The filing receipt for this application inaccurately states that only one independent claim was filed within the application. That is incorrect. There are two independent claims -claims 16 and 21. This preliminary amendment clarifies that claim 21 is an independent claim and, in particular, the reference in claim 21 to cancelled claim 1 has been deleted and substitute language has been added.

In the Notice of Omitted Items, Figure 7B is listed as having been omitted from this application, as filed. In response to this

Notice, applicants have deleted the references to omitted Figure 7B in the drawings and specification. Accordingly, Figure 7A has been renumbered as Figure 7 on the enclosed corrected sheet of formal drawings, and a sketch is included showing the drawing corrections circled in red. In the specification, the references to Figure 7B have been deleted and a replacement paragraph has been provided, which does not add any new matter. A copy of the Notice of Omitted Items is enclosed.

It is believed that no fee is associated with this request. However, if any fee is due the Examiner is hereby authorized to charge Deposit Account No. 50-1039.

Respectfully submitted,

Date: January 24, 2002

By:

  
Gary W. McFarron, Esq.  
Registration No. 27,357  
Cook, Alex, McFarron, Manzo,  
Cummings & Mehler, Ltd.  
200 West Adams St., Suite 2850  
Chicago, IL 60606  
Telephone: (312) 236-8500

Attorneys for Applicant

Marked-Up Version of the Specification to Show Changes Made

As illustrated in Fig. 7 [Figs. 7A and 7B], the access tube 50 can be used to access a pericardial space PS from a subxiphoid approach. A patient's heart H underlies the sternum S beneath the chest wall CW, as illustrated in Fig. 7 [Fig. 7A]. The access tube 50 can be introduced beneath the inferior end of the sternum S to approach the parietal pericardium PP[, as illustrated in Fig. 7B]. The penetrating elements 56 can thus engage the parietal pericardium and draw it away from the visceral pericardium VP[, also as shown in Fig. 7B]. The access device 14 can then be introduced through the access tube 50 and into the enlarged pericardial space PS'. The access device 14 can be used for introducing a guidewire or any of the other purposed described above.

Marked-Up Version of Claim 21 to Show Changes Made

21. (Amended) A kit for accessing the pericardial space between the visceral and parietal pericardium, said kit comprising:

an access tube having a distal end which can be selectively embedded into tissue; and

instructions for use setting forth a method for accessing an anatomic space having a wall with an outer surface, said method comprising:

embedding a distal end of an access tube into the outer surface;

drawing the access tube proximally to raise the wall over the anatomic space and to enlarge the anatomic space; and

introducing an access device through the access tube, penetrating the wall and into the anatomic space while the access tube stabilizes the wall [as in claim 1].

FIG.5E

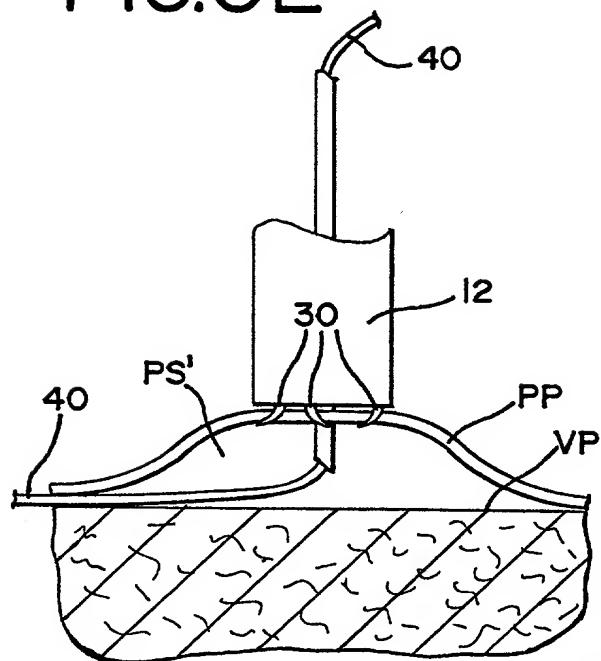


FIG.5F

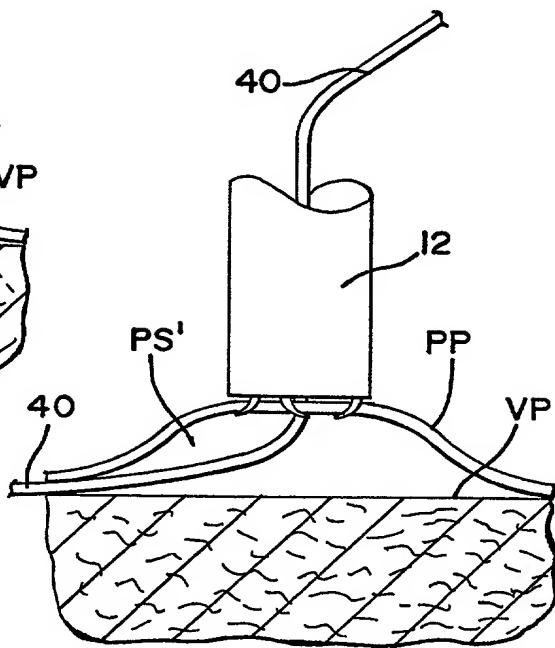


FIG.6

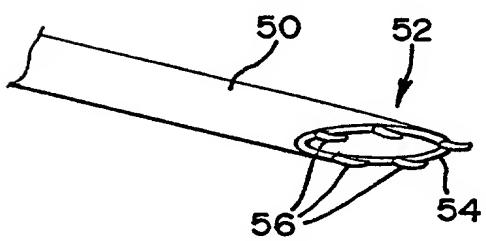
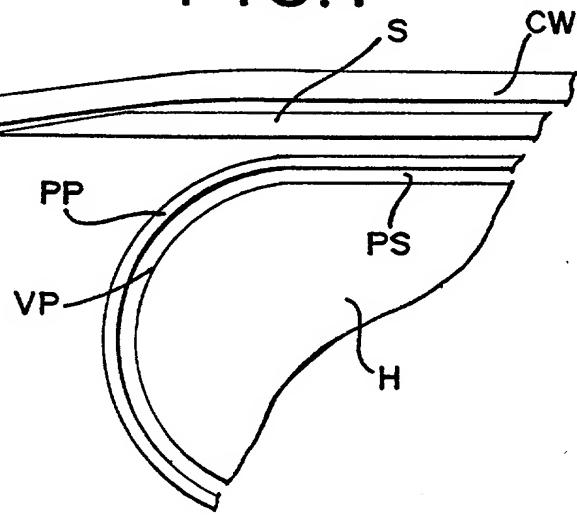
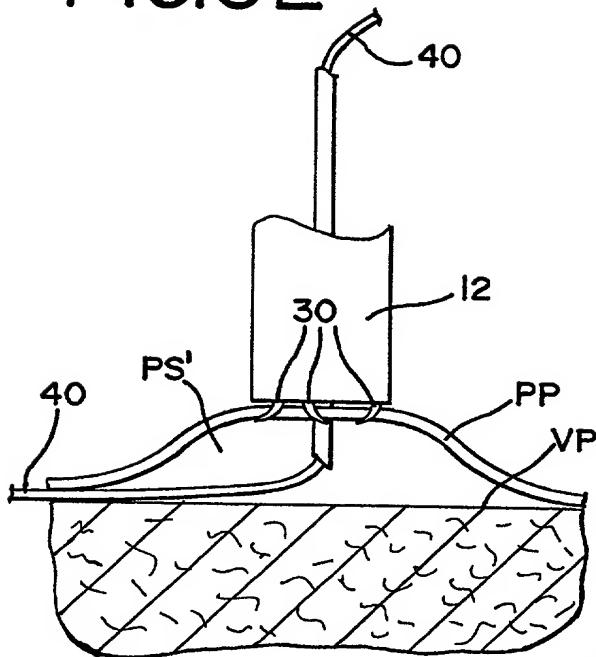


FIG.7



## FIG.5E



**FIG.5F**

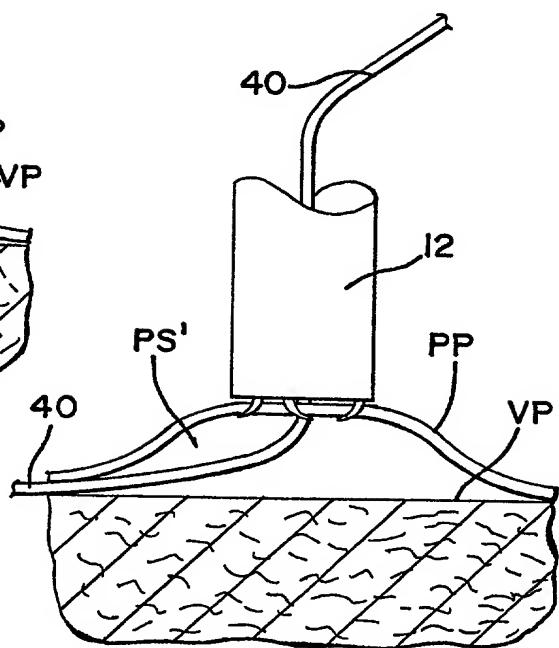


FIG.6

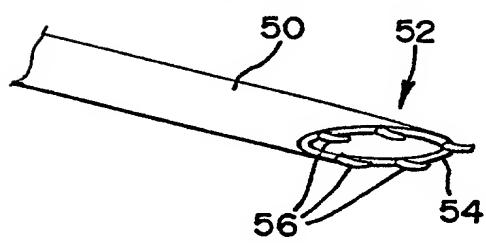


FIG. 7A

